REMARKS

Applicant has amended claims 1-11, 22, 24 and 26. Claims 11-15, 17-19 and 22-25 have been allowed. Claims 33-52 have been added. Claims 20 and 21 have been cancelled without prejudice. Claims 1-15, 17-19, 22-26 and 33-52 are in the application.

The Examiner had rejected claims 1-5 and 7 under 35 USC § 112, paragraphs 1 and 2, because of the insertion of the term "independent", referring to the paths through the sample. The term has been deleted from the claims and, accordingly, the rejection is rendered moot.

Claims 11-15, 17-19 and 22-25 have been allowed. Minor changes have been made to those claims for purposes of clarity only. No new matter or substantive changes have been made which would affect the allowance of those claims.

Independent method claim 1 and the independent apparatus claim 7 have been amended to more particularly point out applicant's invention and to further distinguish applicant's invention from the prior art. The method claim 1 and the apparatus claim 7 concern optical interactance measurements, that is, optical measurements within a volume of material underlying the material surface (the interior portion of the material), which exclude measurements of optical energy reflected by the surface. In other words, the surface area for illumination is distinct from where the energy exits.

As now set forth in claim 1, the invention relates to a method for improving optical interactance measurements comprising the steps of passing illumination along a plurality of different paths through an interior portion of a material having a characteristic to be measured. This is accomplished by defining each of the paths by two distinct surface areas of the material. At least one of the surface areas of one of the paths is extended in length at substantially constant spacing from the other surface area of the one path. The method also includes the step of sensing a plurality of independent signals developed at the same time or in rapid sequence representing optical information obtained from within the material in response to the illumination passing along the different paths. Each independent signal corresponds to a particular path. Finally, the method encompasses processing the signals in accordance with appropriate modeling techniques to determine qualitative or quantitative characteristics of the material.

As now amended, claim 7 relates to apparatus for optical interactance measurements of an interior portion of a material. Such measurements are effected by passing illumination through different portions of the material. The apparatus comprises aperture means for defining corresponding distinct illumination and detection surface areas for each of a plurality of transmission paths within the material. At least one surface of at least one of the transmission paths extends in a direction substantially transverse to the direction of illumination passage

along the one transmission path and is substantially constantly spaced from its corresponding surface area. Means are included for directing illumination onto the illumination surface areas and along the transmission paths. Means are also included for sensing optical information developed by illumination passing along the transmission paths at the detection surface areas of the transmission paths. Means, responsive to the sensing means, form part of the apparatus for developing a plurality of independent signals corresponding in number to the plurality of paths. The signals represent the optical information obtained from the material. Finally, means are included for processing the signals in accordance with appropriate modeling techniques to determine quantitative or qualitative characteristics of the material.

The essence of the claimed invention thus lies in making separate optical measurements utilizing at least two optical paths which have different mean path lengths through partially overlapping measurement volumes within the material and which are arranged to maximize the measurement volume of each path. This is achieved by extension of one of the paths in a direction transverse to the direction of illumination and by having the related surface areas being at substantially constant spacing from each other. Using two or more optical paths at different paths within the material, which share a portion of their respective measurement volumes, provides the information needed for the processing of the optical measurement signals to

remove effects common to the paths, including the characteristics of the illuminating surface, the measuring instrument and the surface layers of the material through which all of the paths pass. The effective depth of penetration is a function of the path length through the material. Therefore, it is possible to control the effective depth of measurement and substantially reduce the effects of material closer to the surface by combining shallow and deep measurements. Adding additional paths increases the number of variables available for multivariate modeling of the signal characteristics which consequently improves the ability of the signal processing to handle non-linearities and to differentiate between various interferences and the desired signals. Maximizing the measurement volumes of the different transmission paths substantially improves the accuracy of the measurement by reducing the effects of sample inhomogeneity on the optical measurements. Extending the aperture as taught by the applicant increases the measurement volume and maximizes the energy transmission so as to improve the measurement signal to noise ratio.

The preferred embodiment of this invention as described in the specification comprises concentric ring apertures for illumination and a smaller area centrally located aperture for detection which is common to all paths. Several advantages are inherent to this embodiment. This arrangement is particularly suited for efficient transfer of optical energy from a source such as tungsten-halogen lamp to a detection system with a

limited throughput such as a spectrophotometer. A typical projection lamp with a built-in reflector, for example, ANSI type EPT, provides one centimeter diameter illumination at a numerical aperture of about 0.5. This allows efficient illumination of the larger area surface regions provided by the concentric rings using high numerical aperture fiber optic bundles. The area of a ring of fixed width is proportional to its circumference so the outer rings defining the larger path lengths have greater area than the inner rings, thereby providing additional energy to partially compensate for the increased losses associated with the larger path length. A typical small diode array spectrophotometer, however, exhibits a numerical aperture of approximately 0.2 and an entrance slit area of about 1 square millimeter. A small central detection region can match this much lower throughput so its size is not a disadvantage. In addition, the noise of optical detectors is typically proportional to the square root of the detector area. This configuration thereby inherently maximizes the energy transfer through the sample from the source into the spectrophotometer and minimizes the detector noise thereby providing superior signal to noise ratio for the measurement signals. Therefore, the Examiner will appreciate that these factors are contrary to the usual assumption that the use of opposing directions along a path are equivalents.

In addition, detection of stray optical energy through the central detection aperture is inherently greatly reduced due

to its lower throughput and greater distance from the ambient environment compared to the surrounding source rings.

In the preferred structure, there is a single detection system which is common to all the paths. This has the advantage of ensuring that the characteristics of the detection system are identical for all paths, which reduces errors in comparing the measurement signals from the various paths. Signals from the various paths are then identified and separated based on optical intensity modulation applied at the source. The energy from the single source lamp can be divided and intensity modulated before it is transmitted to the illuminating apertures, also ensuring that the source optical characteristics are common to all the paths. This modulation can be accomplished by a suitably configured optical chopper which replaces the simple on-off chopper that is typical of other systems at little additional cost. As additional detection systems are typically more expensive than the inventive source arrangement, the preferred embodiment provides an advantage in being more cost effective.

Another aspect of the preferred structure of the invention is the flexibility in measurement geometry it provides. When not in contact with the material to be measured, the source energy is directed towards an axis which is perpendicular to and centered on the detection aperture at an angle of about 45° to the axis. This provides a region of intense illumination on the axis at a distance from the detection aperture approximately equal to the radius of the source aperture. This region

encompasses the field of view of the detection optics allowing diffuse reflectance measurements to be made on small objects. The measurement region may be further controlled by the addition of lenses to image the sample surface on the detection aperture with selected magnification. This flexibility is particularly valuable for medical use because it allows either subcutaneous or surface measurements to be performed using the same instrumentation (see claim 35). Research indicates valuable diagnostic information of both quantitative and qualitative nature can be obtained in this way. Further, flexibility is provided by adding either an auxiliary detector or an auxiliary source at the far side of the sample thereby combining a diffused transmission measurement through the sample with the interactance or reflectance measurement provided by the basic structure.

The Examiner had rejected claims 1, 2, 7 and 8 under 35 U.S.C. § 102 as being anticipated by Howarth. As explained above, the independent claims 1 and 7 have been modified to point out applicant's invention and to further distinguish it from Howarth. In the context of the newly drawn independent claims, Howarth does not teach or suggest using the combination of two or more optical paths each defined by two regions at the surface of the sample, at least one of which is extended transverse to the illumination and direction at substantially constant spacing from the other region.

Howarth's configuration, using a linear arrangement of one source and two detection windows (Fig. 7) which provides two

paths, is described only in reference to a specific consistency measurement. It provides no suggestion of the advantages of the present invention which uses a single detector, and Howarth's source chopper does not provide modulation that identifies the signals from different paths. Further, there is no disclosure in Howarth that the surface area defined by the source and detection regions (windows) of one path lies above the equivalent surface area of the other path as is inherent in the inventive approach of applicant in the use of a larger measurement volume which can be obtained by elongation of one of the measurement apertures. Applicant's approach maximizes the equivalence of the measurements along the different paths, particularly for inhomogeneous materials, while maintaining the advantages of different path lengths. Still further, applicant's concentric or parallel configurations of extended surface regions for illumination, measurement, or both, increase the amount of optical energy transmitted from source to detector and, therefore, the signal to noise ratio of the measurement, by allowing greater optical throughput simultaneously with optimum spacing based on the optical characteristics of the material. This is particularly important for measurements of a low concentration analyte in a highly scattering and absorbing matrix, for example, the determination of blood glucose concentration through the skin of a human being. This is nowhere suggested in Howarth. It is also useful, as applicant's have disclosed, to choose the spacing between the source and detection

surface regions based on the depth of penetration within the material that is desired which is contrary to Howarth's teaching that the spacing is determined based on minimizing the effects of the consistency of the flowing material. Thus, if anything, Howarth teaches away from an important aspect of applicant's invention.

Howarth mentions modification of the shape of the source and detector radiation transmission channels of a single path embodiment of Figs. 10a through 10c in the case of flowing materials to minimize noise in the material and for the averaging out of irregularities. As is illustrated in his example, this modification could be of a rectangular configuration with the long axes of the rectangles being parallel to the direction of flow. This will provide a longer dwell time for the flowing material in a single measurement path, thereby reducing noise and averaging out irregularities. Howarth does not teach or suggestion any reason to modify his dual detector consistency measurement of his Fig. 7 to arrive at applicant's claimed invention.

Based on the above, it is submitted that claims 1 and 7 clearly and patentably distinguish over the teachings of Howarth which neither recognized the problems sought to be overcome by the applicant herein nor provides any teaching or suggestion for their solution. All claims dependent on method claim 1 should therefore be allowed as well, for example, claims 2-6 and added claims 33-35. Similarly, claims dependent from claim 7 should

also be allowed for the reasons set forth above, in particular, claims 8-10 and new claims 36-42.

Claim 43, a new independent claim, covers an important aspect of applicant's invention which had not been previously claimed. While certain features are also set forth in claim 7 (i.e., that there are optical means for defining at least one illumination surface area and at least one detection surface area which are distinct), other features point out that the same instrument can be used for interactance and reflectance measurements in succession. In particular, the claim requires optical means, when the apparatus is disposed at a first predetermined distance from a surface of the material, for defining at least one illumination surface area and at least one detection surface area which are distinct and, when disposed at a second predetermined distance for defining illumination and detection surface areas which are at least partially superimposed. The optical means includes means for illuminating the illumination area and for detecting optical information received from the detection area. Further included are means for processing signals detected by the optical means in accordance with appropriate modeling techniques to determine quantitative or qualitative characteristics of the material. This claim and all claims dependent therefrom, claims 44-52, should also be allowed for the reasons set forth above.

The Examiner rejected claim 20 under 35 U.S.C. § 102(b) as being anticipated by Tachibana. That claim has now been cancelled and, accordingly, the rejection is rendered moot.

The Examiner also rejected claims 1, 2, 7, 8, 20 and 21 under 35 U.S.C. § 102(b) as anticipated by Borsboom. Claims 20 and 21 have been cancelled. It is also clear that the modifications to claims 1 and 7 further distinguish applicant's invention from Borsboom. Borsboom does not provide two paths defined by two distinct surface areas nor is one of these paths extended relative to the other as does applicant. There is a central path in Borsboom which is bidirectional which includes, primarily, surface measurement and the structure is arranged for obtaining surface or reflectance information (see col. 2, lines 37-41 - "The back scattered light collected by the illuminating fiber will have covered a short path in the material being investigated, and be hardly, if at all, absorbed."). Borsboom therefore does not teach the possibility of having two interactance paths as set forth by applicant in claims 1 and 7. It is abundantly clear, furthermore, that Borsboom does not teach or suggest solving the problems sought to be solved by applicant in his inventive structure. Accordingly, this rejection clearly does not properly lie. Again, all claims dependent on claims 1 and 7 should be allowed for the reasons discussed above.

Claim 26 has been rejected under 35 U.S.C. § 103 as being unpatentable over Venable and Gerber in view of Lebling et al. This claim has been limited to interactance and

transmittance measurements only and it should be noted that Venable and Lebling provide multiple paths but are limited to reflectance measurements. In these references, the region illuminated is the same for all paths. An important aspect of this embodiment of the invention has been brought out in a second "whereby" clause which states "whereby surface phenomena of said material may be excluded during measurement". Based on claim 26 as now amended, this claim should also be allowed over the prior art which neither teaches nor suggests its construction.

An Information Disclosure Statement accompanies this Amendment setting forth the results of the European search.

Based on the above, it is submitted that all of the issues in this case have been resolved and that the application should now pass to issue.

Respectfully submitted,

McAULAY FISHER NISSEN
GOLDBERG & KIEL

By: Gerald H. Kiel
Gerald H. Kiel
Reg. No. 25,116

261 Madison Ave.
New York, New York 10016
Tel. (212) 986-4090
GHK:jl